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10/812,387

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Hephzibah Sivaraman

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06/06/2006

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EXAMINER

ROBINSON, HOPE A

ART UNIT

PAPER NUMBER

1656

DATE MAILED: 06/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                                      |   |  |
|------------------------------|--------------------------------------|---|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/812,387 | <b>Applicant(s)</b><br>SIVARAMAN ET AL. |  |
|                              | <b>Examiner</b><br>Hope A. Robinson  | <b>Art Unit</b><br>1656                 |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 23 September 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 September 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>7/20/05:3/16/05</u> | 6) <input type="checkbox"/> Other: _____  |

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## **DETAILED ACTION**

### ***Application Status***

1. The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1656.

2. The Amendments filed on March 30, 2004 and September 23, 2004 have been received and entered.

### ***Claim Disposition***

3. Claims 1-9 are pending and are under examination.

### ***Specification***

4. The specification is objected to because of the following informalities:

(a) The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. The following is suggested: "A Process for the Production of Large Amounts of Penicillin V Acylase using Recombinant Plasmids".

(b) On page 5, line 20, the following typographical error appears, "antibiotic30-50..."

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(c) On page 2 and throughout the specification, the sequence notation is incorrect, where it is disclosed as "SEQ ID No.1" instead of "SEQ ID NO:1". See also the abstract.

(d) The specification is objected to because the ATCC address provided is incorrect and should be the Manassas, VA address.

(e) It is noted that three of the inventor list their citizenship as "Indian" instead of "India". It is suggested that this is corrected as the country of citizenship is what is expected and note that the other inventors listed the country, United Kingdom.

Correction is required.

### ***Drawing***

5. The drawings filed on September 23, 2004 are objected to because Figure 1 and Figure 2 appear to be the same figure. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after

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the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### ***Claim Objection***

6. Claims 1-3, 5-6 and 8 are objected to because of the following informalities:

Claim 1 is objected to because of the reference to Figure 1 in the claim. The claim should be amended to recite the pertinent information found in the figure and the structure of the plasmid, for example, "A recombinant plasmid comprising the nucleotide sequence set forth in SEQ ID NO:1".

Claims 1-2 and 5 are objected to because the claims recite "SEQ ID No.1", which is improper and should be "SEQ ID NO:1".

Claim 3 is objected to as the spelled out meaning for the cell strain is not recited in the claim, see "*E. coli*" which should be "*Escherichia coli*". See also claim 6.

Claim 5 is objected to because the article "the" is missing following "comprises" in line 1 of the claim.

Claim 6 is objected to because the article "the" is missing following "using" in line 1 and "comprising" in line 2 of the claim. In addition, for clarity and precision of claim language it is suggested that the claim is amended to read "A process for the production

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of large amounts of Penicillin V acylase...". Note that the article "a" is missing following the words "medium for" in item (c) of the claim.

Claim 8 is objected to for the recitation of "sodium chloride of concentration ranging between 3-5" and the claim doesn't given any units of measurement.

Correction of the above is required.

### ***Information Disclosure Statement***

7. The Information Disclosure Statements filed on March 15, 2005 and July 20, 2005 have been received and entered. The references cited on the PTO-1449 Form have been considered by the examiner and a copy is attached to the instant Office action.

### ***Claim Rejections - 35 U.S.C. § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 1-9 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and or use the invention. The specification does not contain the required

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information for a deposit (see page 6). Use of the claimed invention requires deposited material, but deposit of material does not ensure that it will readily be available during the duration of the patent. Applicant's deposit would satisfy the enablement requirements of 35 U.S.C. 112, provided that the following conditions are met. It is noted that the specification on page 6 indicates that a" the present invention provides a new strain of E. coli namely PTA 2456". Page 6 also discloses that said strain is deposited at ATCC, however, no date is provided or the ATCC number. No information regarding public availability is provided or if the deposit was made under the Budapest Treaty. Thus, the invention is not adequately described and one skilled in the art would not have access to the necessary materials to be able to practice the claimed invention. Applicant makes reference to the deposit number (note that the deposit number is missing on page 96 of the specification), however, this is not sufficient to illustrate that the information is publicly available or give the assurance that all of the conditions of 37 CFR 1.801-1.809 have been met. If deposits have not been made under the Budapest Treaty, then in order to certify that the deposits meet the criteria set forth in 37 CFR 1.801-1.809, applicant may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number, showing that:

(A) During the pendency of this application, access to the invention will be afforded to the Commissioner upon request;

(B) All restrictions upon availability to the public will be irrevocably removed upon granting of the patent;

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(C) The deposits will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer;

(D) The deposits were viable at the time of deposit;

(E) The deposits will be replaced if they should ever become non-viable.

This requirement is necessary when a deposit is made under the provisions of the Budapest Treaty as the Treaty leaves these specific matters to the discretion of each member State. Amendment of the specification to disclose the date of the deposit and the complete name and address of the depository is required. For further information concerning deposit practice, applicants attention is directed to In re Lundark 773 F 2d 1216 227 USPQ CCAFC and 37 CFR 1.801-1.809.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

9. Claims 1-9 are rejected under 35 U.S.C. 112, second paragraph, as failing to set forth the subject matter, which applicant (s) regard as their invention.

Claim 1 is confusing because the claim does not have a proper Markush grouping and it is unclear what numbers 1-5 refer to, if this is intended to be the order in the plasmid. It is suggested that the claim is amended to read, "A recombinant plasmid comprising the nucleotide sequence set forth in SEQ ID NO:1". See also claims 5-6.



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Claim 2 is indefinite for the recitation of Figure 2 and the indication of it being a gene, because the present figures do not reflect that, for example no structure for the gene is shown, just an arrow as to where the gene would be inserted. It is suggested that reference to Figure 2 is deleted from the claim.

Claim 3 is indefinite for the recitation of "A recombinant *E. coli* strain PTA 2456" because there is no nexus made between this claim and the claimed invention.

Claim 4 lacks antecedent basis for the recitation of "recombinant stain". In addition, the claim is indefinite for the recitation of "ordinary conditions", it is suggested that the term is deleted and replaced with a "control" comparison. See also claim 7.

Claim 8 is indefinite for the recitation of "between 3-5" and there is no units to indicate what is being measured.

### ***Art of Record***

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Muchova et al. (Microbiology, vol. 148, pages 807-813, 2002) teach a insertion of a nucleic acid into a plasmid (pET26b(+)) and the introducing NdeI and BamHI sites. However, the reference does not teach SEQ ID NO:1 as claimed.

### ***Conclusion***

11. No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hope A. Robinson whose telephone number is 571-272-0957. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr, can be reached at (571) 272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Hope Robinson, MS

Patent Examiner

**HOPE ROBINSON  
PATENT EXAMINER**

*AR*  
*5/30/06*